UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/049,227	03/27/1998	MARTIN P. REDMON	4821-304	5249

7590 10/03/2003

PENNIE & EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 10/03/2003

32

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/049,227	REDMON ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12-18,21-25,28-30 and 33-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 12-18, 21-25, 28-30, 33-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

1. Claims 1-9, 12-18, 21-25, 28-30, 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over El-Rashidy et al., supra in view of Young et al., 5,104,899 and WO 97/28788 ('788) (submitted by Applicant).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to Applicant's amendment received March 25, 2003.

Claims 10, 11, 19, 20, 26, 27, 31, 32 are cancelled. No new claims are added. Claims 1-9, 12-18, 21-25, 28-30, 33-37 are currently pending.

The previous claim rejection under 35 USC 102(e) set forth in paragraphs II-III of the office action mailed Sep. 26, 2002 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous claim rejection under 35 USC 103(a) set forth in paragraphs IV-VI of the office action mailed Sep. 26, 2002 have been considered but are not found to be persuasive. Please note that the Examiner has withdrawn the Young et al. 5,648,396 patent from the rejection. The claims are now drawn to compositions containing (S)-fluoxetine and the disclosure in the '396 patent is directed to (R)-fluoxetine.

Said rejection is maintained essentially for the reasons given previously in the office action mailed Sep. 26, 2002 with the following additional comment:

It is Applicant's position that the prior art does not disclose or fairly suggest Applicant's claimed compositions and method. Specifically, Applicant argues that the prior art of record does not disclose pharmaceutical compositions containing (S)-fluoxetine, which are lactose free or anhydrous. Applicant contends that the compositions disclosed in the '500 patent just happen to contain no lactose. There is no disclosure or suggestion in '500 that lactose should be avoided in the fluoxetine containing compositions. Moreover, '500 is completely silent as to the advantages associated with fluoxetine compositions that are lactose free.

Concerning the claims drawn to anhydrous compositions containing fluoxetine, Applicant argues that '500 is directed to a "dry process" of making the disclosed fluoxetine containing composition. However, this does not necessarily mean that the resulting compositions are anhydrous. Applicant points out the process in '500 ignores atmospheric water and dry processes of making the compositions would not result in an anhydrous composition if precautions were not taken to prevent atmospheric water from being incorporated into the compositions.

Finally, Applicant argues that the claimed dissolution times are not art-recognized result-effective variables. Based on the disclosure of the '500 patent, one of ordinary skill in the art would not have been motivated to arrive at the claimed invention. Absent a disclosure directed to the advantages of the dissolution time recited in the claims, one of ordinary skill in the art would not have been motivated to try to obtain the invention as claimed.

Said arguments have been considered but, respectfully, are not found to be persuasive.

The Examiner respectfully maintains that the prior art renders obvious the claimed invention. Specifically, the Examiner respectfully submits that disclosure discussing the advantages of fluoxetine compositions which are free of lactose is not necessary because '500 discloses compositions, which do not contain lactose. The teachings of '500 suggests to one of ordinary skill in the art that fluoxetine compositions not containing lactose are useful and effective pharmaceutical compositions.

Concerning Applicant's arguments with respect to the claimed anhydrous compositions, the Examiner respectfully maintains that this is obvious in view of El-Rashidy's ('500) teachings. Applicant's specification at page 15, lines 27-33 defines "anhydrous" as substantially free of unbound water or the amount of unbound water (if present) is insufficient to accelerate incompatibility between fluoxetine and lactose. Applicant has previously contended that El-Rashidy discloses a fluoxetine composition containing an ingredient, dicalcium phosphate dihydrate, which contains water . Therefore, the disclosed compositions cannot be anhydrous. However, the Examiner respectfully maintains that the term "anhydrous" as defined does not exclude all water (substantially free of water) and further that the water molecules appear to be bound to the dicalcium phosphate and therefore would not be expected to detrimentally affect the overall composition. Applicant's arguments do not appear to distinguish the compositions in '500 from the claimed compositions by explaining how the water-

containing dicalcium phosphate dihydrate detrimentally affects the overall fluoxetine composition.

Finally, although '500 does not disclose the advantages of the dissolution time recited in the claims, the Examiner respectfully maintains that the dissolution time of a tablet is an art-recognized result-effective variable. This is further demonstrated by WO '788, which discloses that dissolution time is one of several known physical characteristics of a tablet (page 3, last three lines). The harder a tablet is the more time it takes to dissolve (page 4, first full paragraph). Absent evidence to the contrary, it would be obvious to one of ordinary skill in the art to further modify the fluoxetine compositions until a desired dissolution time, i.e. "not less than three minutes" or "more than five minutes", is acquired thereby resulting in a therapeutically efficacious pharmaceutical composition.

It is for these reasons that the rejection is maintained.

Conclusion

Claims 1-9, 12-18, 21-25, 28-30, 33-37 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Tue-Thur. from 8:30 to 6:00. The examiner can also be reached on alternate Mondays .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725 The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

DWAYNE C. JONES
PRIMARY EXAMINER

CDM

Sep. 30, 2003